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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/540,764	11/14/2005	Filippo Bastia	BUG8-38328	9211		
116	7590	02/20/2008	EXAMINER			
PEARNE & GORDON LLP 1801 EAST 9TH STREET SUITE 1200 CLEVELAND, OH 44114-3108				KASZTEJNA, MATTHEW JOHN		
ART UNIT		PAPER NUMBER				
3739						
MAIL DATE		DELIVERY MODE				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/540,764	BASTIA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	MATTHEW J. KASZTEJNA	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 1/24/08.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 27-51 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 27-31,36,37 and 39-51 is/are rejected.  
 7) Claim(s) 32-35 and 38 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 24 June 2005 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/24/08</u> .   | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 24, 2008 has been entered.

### ***Notice of Amendment***

In response to the amendment filed on January 24, 2008, amended claims 27-28, 30-39, 44-45, 48 and 50 are acknowledged. The following new grounds of rejection are set forth:

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27, 40-44 and 48-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1,234,539 to Gmbh in view of U.S. Patent No. 348,843 to Hamilton in further view of U.S. Patent No. 4,819,620 to Okutsu.

**In regards to claims 27, 40-44 and 48-51,** Gmbh discloses a disposable device for surgical operations on the arteria haemorroidalis (FIG. 1) comprising a retractor tube

closed and rounded at the end (tube 1 in FIG. 1), which is provided upon its side surface with at least a window (7 in FIG. 1), a gripping handle; means to illuminate said window (light guide 10 in FIG. 2), said illumination means comprises a luminous source (LED 5 in FIG. 1) fixed in removable manner inside said handle (see. FIG. 4 and paragraph 20: handle 2 including LED can be removed) and comprise at the level of the conjunction zone of the handle to the external end of the retractor tube, means to reflect the light supplied from said source and to allow that the said reflected light illuminates the internal portion of the retractor tube and particularly said lateral window (light guide 10 in FIG. 1). The arrangement also has a proximal region (3) where the hand grip is located, and a distal region (4) containing an ultrasound probe (6) for localizing an artery and an opening (7). Gmbh is silent with respect to the retractor tube having an internal chamber at least partially defined by a wall integral with internal walls of the retractor and having an opening toward the mouth of the retractor through which the ultrasonic probe may be inserted. Hamilton teaches of an analogous device having an internal chamber 4 through which instruments may be passed to treat a desired site within the body (see Figs 4-6 and Col. 1, Lines 55-100). It would have been obvious to one skilled in the art to provide an internal chamber upstream of the exploration window in the apparatus of Gmbh to provide additional opening means for inserting instruments to a desired site within the body as taught by Hamilton.

With further respect to claim 27 and the device of Gmbh and Hamilton, Okutsu teaches of an analogous apparatus having an observation window 12f and a slot 12c (see Fig. 5 and Col. 4, Lines 18-43). Thus Okutsu demonstrates that it is well known in

the art to have both an observation window and an additional opening through which surgical instruments may be passed, which is separate from the observation window. It then would have been obvious to pass the ultrasonic probe of Gmbh through the internal chamber as described by Hamilton, to obtain direct contact at a desired site within the body as taught by Okutsu.

Claims 28-31, 36-37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1,234,539 to Gmbh in view of U.S. Patent No. 348,843 to Hamilton in further view of U.S. Patent No. 4,819,620 to Okutsu in further view of FR 2,623,078 to Gilles.

**In regards to claims 28-31, 36-37 and 39,** Gmbh, Hamilton and Okutsu disclose a disposable device for surgical operations on the arteria haemorroidalis (FIG. 1) comprising a retractor tube closed and rounded at the end (tube 1 in FIG. 1), which is provided upon its side surface with at least a window (7 in FIG. 1), a gripping handle; means to illuminate said window (light guide 10 in FIG. 2), said illumination means comprises a luminous source (LED 5 in FIG. 1) fixed in removable manner inside said handle (see. FIG. 4 and paragraph 20: handle 2 including LED can be removed) and comprise at the level of the conjunction zone of the handle to the external end of the retractor tube, means to reflect the light supplied from said source and to allow that the said reflected light illuminates the internal portion of the retractor tube and particularly said lateral window (light guide 10 in FIG. 1). Gmbh, Hamilton and Okutsu are silent with respect to a specular parabola. Gilles teach of an analogous apparatus wherein a mirror is used as means to reflect light in a (see page 3, lines 29-32). The choice of a

parabolic mirror as a specifically formed mirror comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. It would have been obvious to one skilled in the art at the time the invention was made to include a parabola in the apparatus of Gmbh, Hamilton and Okutsu, to distribute light more efficiently within the device as taught by Gilles.

Claims 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1,234,539 to Gmbh in view of U.S. Patent No. 348,843 to Hamilton in further view of U.S. Patent No. 4,819,620 to Okutsu in further view of U.S. Patent No. 5,570,692 to Morinaga.

**In regards to claims 45-47,** Gmbh, Hamilton and Okutsu disclose a disposable device for surgical operations on the arteria haemorroidalis (FIG. 1) comprising a retractor tube closed and rounded at the end (tube 1 in FIG. 1), which is provided upon its side surface with at least a window (7 in FIG. 1), a gripping handle; means to illuminate said window (light guide 10 in FIG. 2), said illumination means comprises a luminous source (LED 5 in FIG. 1) fixed in removable manner inside said handle (see. FIG. 4 and paragraph 20: handle 2 including LED can be removed) and comprise at the level of the conjunction zone of the handle to the external end of the retractor tube, means to reflect the light supplied from said source and to allow that the said reflected light illuminates the internal portion of the retractor tube and particularly said lateral window (light guide 10 in FIG. 1). Gmbh, Hamilton and Okutsu are silent with respect to a curved needle being located inside of the retractor tube under an exploration window.

Morinaga teaches of an analogous device comprising an ultrasonic doppler blood flow detector used for hemorrhoid artery ligation having a hollow insertion cylinder which is enclosed at the distal end and open at the near end, and can be inserted through the anus; the cylinder has an ultrasound transducer in its interior wall, for detecting blood flow in the affected artery, and a ligation hole next to the transducer, through which the detected artery is ligated with ligation device, such as a curved needle or a wire for cautery (see Figs. 1-3). It would have been obvious to one skilled in the art at the time the invention was made to include a curved needle in the apparatus of Gmbh, Hamilton and Okutsu to effectively treat diseased tissue as taught by Morinaga.

***Allowable Subject Matter***

Claims 32-35 and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

Applicant's arguments with respect to claim 27 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW J. KASZTEJNA whose telephone number is (571)272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. J. K./  
Examiner, Art Unit 3739

/Linda C Dvorak/  
Supervisory Patent Examiner, Art  
Unit 3739

2/13/08